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TITLE: "USASOC Injury Prevention/Performance Optimization Musculoskeletal Screening Initiative"

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RECIPIENT: Dr. Christie Vu

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14. ABSTRACT One of the most important determinants of military readiness for USASOC is the health and well-being of its personnel as many suffer a multitude of preventable musculoskeletal injuries due to the daily rigors of physical training and preparation for tactical operations. Physical training remains the cornerstone of the weapons platform of USASOC personnel, yet a significant number of injuries are sustained during Command instructed physical training. The Tactical Human Optimization, Rapid Rehabilitation, and Reconditioning (THOR3) training program was established to improve functional performance and combat effectiveness, reduce lost manpower, and optimize recovery and reconditioning between deployments. As such, the purpose of this study is to measure the effectiveness of the THOR3 human performance training program to improve upon biomechanical, musculoskeletal, physiological, performance, tactical and injury mitigating characteristics and to reduce unintentional musculoskeletal injuries.		

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TABLE OF CONTENTS

	<u>Page No.</u>
1. Introduction	5
2. Keywords	5
3. Accomplishments	5
4. Impact	9
5. Changes/Problems	10
6. Products	12
7. Participants & Other Collaborating Organizations	15
8. Special Reporting Requirements	18
9. Appendices	19

1. INTRODUCTION:

One of the most important determinants of military readiness for USASOC is the health and well-being of its personnel as many suffer a multitude of preventable musculoskeletal injuries due to the daily rigors of physical training and preparation for tactical operations. Physical training remains the cornerstone of the weapons platform of USASOC personnel, yet a significant number of injuries are sustained during Command instructed physical training. The Tactical Human Optimization, Rapid Rehabilitation, and Reconditioning (THOR3) training program was established to improve functional performance and combat effectiveness, reduce lost manpower, and optimize recovery and reconditioning between deployments. As such, the purpose of this study is to measure the effectiveness of the THOR3 human performance training program to improve upon biomechanical, musculoskeletal, physiological, performance, tactical and injury mitigating characteristics and to reduce unintentional musculoskeletal injuries.

2. KEYWORDS:

Injury prevention; Musculoskeletal Injury; Performance Optimization; USASOC, THOR3

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Major Task 1: Administrative & Regulatory

- Milestone: University of Pittsburgh IRB Approval. Approved May 23, 2016. 100% Complete
- Milestone: Set up Data Use Agreement. UPitt has completed the DUA application and it is being sent to MRMC, SOCOM and USAOC POC's.
- Milestone: HRPO Approval. Approved July 28, 2016, 100% Complete

Major Task 2: Coordinate Logistics for the Research Trials

- Milestone: Research staff trained, 3 months. 2 Research staff trained and relocated to Fort Bragg. Hired 3rd person, however she has not relocated yet due to hold on the research account by USMRAA. 70% Complete
- Milestone: Pitt Remote Laboratory setup, 3 months. 100% Complete

Major Task 3: Subject Recruitment for the Research Trials

- Milestone: Recruit subjects for participation Phase 3 Aim THOR3 Trial, 4-12 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Recruit subjects for participation Phase 4 Aim 1 THOR3 USASOC wide Trial, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Recruit subjects for participation Phase 4 Aim 2 THOR3 Injury Mitigation Trial, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval

Major Task 4: Phase 3 Aim 1: Data Collection

- Milestone: Completion of baseline measures, 9-15 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Implement experimental protocol, 9-15 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Completion of Clinical Trial Data Collection, 15-18 months

Major Task 5: Phase 4 Aim 1 & 2: USASOC Wide Injury & Injury Mitigation Data Collection

- Milestone: Completion of baseline measures, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Implement experimental protocol, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Completion of USASOC Wide & Injury Mitigation Data Collection, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval

Major Task 6: Data Analysis for Research Aims 3 & 4

- Final Report provided to USASOC Command, 19-24 months
- Presentation of data at National Annual Conferences, 19-24 months
- Minimum of 5 manuscripts published in high impact journals, 19-24 months

What was accomplished under these goals?

Major Task 1: Administrative & Regulatory

- a) Attended In-Progress Review at Fort Detrick on June 7 and 8th. As a result of this review, JPC-5 and CDMRP requested additional information regarding specifics of the proposed statement of work.
 - i) After UPitt, USASOC, MPMC and SOCOM had several telephone meetings to resolve the concerns, a formal written response (including a revised statement of work and memorandum addressing the specific concerns) was submitted to the contracting officer Lance Nowell on June 21, 2016. We are waiting for a response back from USAMPMC or USAMRAA.
 - ii) July 13, 2016 Shannon Hukriede, contracting officer at Pitt called Mr. Lance Nowell regarding the status our revised statement of work submitted June 21, 2016.
 - iii) July 13, 2016 UPitt submitted a letter to Mr. Lance Nowell notifying him of University of Kentucky's decision to end the subcontract with UPitt. The Univ of Pitt requested approval to perform the subcontracted work in-house.
 - iv) July 18, 2016 Mr. Lance Nowell requested UPitt submit a revised budget regarding the change in personnel due to the Univ of Kentucky ending their subcontract.
 - v) July 19, 2016 Mr. Lance Nowell requested a revised statement of work due to the UK change.
 - vi) July 21, 2016 Mr. Ray Bear (3SFG THOR3) notified UPitt of policy change by new Commander at 3SFG mandating ORT for all Operators, and difficulty getting subjects for the study cohorts in Phase 3 as a result of this change.
 - vii) July 22, 2016 UPitt submitted a revised budget and budget justification and revised SOW.
 - viii) August 2, 2016 Shannon Hukriede, contracting officer at Pitt, sent Mr. Nowell an email regarding the status of our revised budget and SOW submitted July 22, 2016.
 - ix) Sept 30, 2016 Shannon Hukriede, contracting officer at Pitt, sent Mr. Nowell an email regarding the status of our revised budget and SOW submitted July 22, 2016.
 - x) October 5, 2016 Mr. Lance Nowell requested additional information regarding specific outcome measures for each of the 4 research aims.
 - xi) October 11, 2016 UPitt provided the requested information.
 - xii) UPitt has provided all requested information on and in most instances in advance of the deadlines. We are still waiting for a response from USAMRAA regarding approval to move forward and initiate work on the Phase 3 and 4 research aims
- b) IRB & DoD Regulatory Approvals
 - i) University of Pittsburgh IRB approved May 23, 2016
 - ii) HRPO USAMPMC approved on July 28, 2016.
- c) A data use agreement is being sent to contracting partners (as per below POCs).
 - i) USAMPMC: Scientific POC: Dr. Richard Shoge Legal POC: Jeremiah Kelly
 - ii) SOCOM: Scientific POC: Dr. Travis Harvey Legal POC: Travis Harvey
 - iii) USASOC: Scientific POC: COL Shawn Kane Legal POC: COL Shawn Kane
 - iv) UPitt: Scientific POC: Dr. Kim Beals Legal POC: Shannon Hukreide

Major Task 2: Coordinate Logistics for the Research Trials

- a) We have identified an individual for the third remote faculty position. We will make a formal job offer once we receive word from USAMRAA and/or USAMPMC we are cleared to move forward. Then we will make arrangements to relocate her.
 - (1) The laboratory is fully operational and awaiting USAMPMC administrative approval before recruiting and testing begins.
 - (2) The UPITT Military Epidemiology Database has been revised and updated to include the proposed outcome variables associated with the research trials (Phase 3 and Phase 4). The need to modify UPittMed will be reevaluated once the SOW is approved.
 - (3) We have developed data collection sheets for the Operator Readiness Assessment, SOCOM Assessment and Body Composition Assessments (ISAK). The need to modify these data collection tools will be reevaluated once the SOW is approved.
 - (4) An Operator Report to provide to subjects with their individual results compared to benchmarks was developed.
 - (5) We have worked with the Public Health Command on the proposed research methods and survey tools for Phase 3 and 4 Aims 1 and 2.

Major Tasks 3-6: We have not initiated work on any of these tasks

What opportunities for training and professional development has the project provided?

UPitt remote faculty have worked with Ray Bear, Human Performance Coordinator for 3rd Special Forces Group, to learn how to administer the Operator Readiness Test and SOCOM Assessment.

How were the results disseminated to communities of interest?

Nothing to report

1. Administrative & Regulatory
 - a. Pending approval of revised statement of work and budget, modify IRB and HRPO documents and submit for approval.
 - b. Complete the Data Use Agreement
2. Relocate the final remote faculty position.
3. Coordinate Logistics for all 3 Research Trials (Phase 3 Aim 1 and Phase 4 Aim 1 & 2)
 - a. Identify which of the research aims require Pitt IRB modification, submit the modifications and await approval. Submit modifications to USAMRAA HRPO and await approval.
 - b. Plan a trip to USASOC to brief remote laboratory, USASOC personnel on the approved protocols and develop a recruiting strategy and study plan and timeline. Begin subject recruitment and testing.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report

What was the impact on society beyond science and technology?

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

On June 7, 2016 the PI presented the protocol at an In-Progress Review to the JPC-5 at Fort Detrick. As a result of this meeting, CDMRP requested additional information with regard to the specifics of the proposed statement of work. The PI submitted a written response, including a revised statement of work addressing the concerns to Mr. Lance Nowell on June 21, 2016. Since this time, there have been several additional requests for information which Pitt provided either before or on the due date set by Mr. Lance Nowell. We are awaiting a response. As a result, there has been a delay (to date ~5 months) in initiating all research aims at Fort Bragg.

Actual or anticipated problems or delays and actions or plans to resolve them

On June 7, 2016 the PI presented the protocol at an In-Progress Review to the JPC-5 at Fort Detrick. As a result of this meeting, CDMRP requested additional information with regard to the specifics of the proposed statement of work. The PI submitted a written response, including a revised statement of work addressing the concerns to Mr. Lance Nowell on June 21, 2016. Since this time, there have been several additional requests for information which Pitt provided either before or on the due date set by Mr. Lance Nowell. We are awaiting a response. As a result, there has been a delay (to date ~5 months) in initiating all research aims at Fort Bragg. Once we have the approval to proceed with the research, we will identify if modifications are required with the Pitt IRB and USAMRMC HRPO and submit these changes. We will initiate subject recruiting and testing on research aims that do not require regulatory modification/approval. Research Phase 4 Aim 2 is a 12-month trial and at this point, will require an extension to the contract end date in order to complete it.

On July 21, 2016 Mr. Ray Bear (THOR3) notified UPitt of a policy change by the new Commander at 3rd Special Forces Group mandating ORT for all Operators, increasing participation to THOR3 and difficulty getting subjects for the study cohorts as a result of this change. Due to the mandated change, Mr Bear and his team at 3rd group indicated they would not have the time to support research effort as originally planned. Proposed solutions to the problem include identifying another USASOC unit at Fort Bragg to participate in Phase 3 Aim 1, possibly the Special Warfare Center and School (SWCS) candidates for Special Forces. This proposed change was submitted within the revised SOW and we are still awaiting a response.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

Not applicable

Significant changes in use of biohazards and/or select agents

Not applicable

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

Nothing to report

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers, and presentations.

Nothing to report

- **Website(s) or other Internet site(s)**

Nothing to report

- **Technologies or techniques**

Nothing to report

- **Inventions, patent applications, and/or licenses**

Nothing to report

- **Other Products**
Examples include:

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Operator Readiness Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Kim Beals
Project Role:	Principal Investigator
Nearest person month worked:	12
Contribution to Project:	Write IRB and IRB resubmission, Lab move and setup, Faculty Hiring, Data Use Agreement, In-Progress review, All planning of research aims
Name:	John Abt
Project Role:	Co-Investigator
Nearest person month worked:	9
Contribution to Project:	Write and review IRB, Involved in laboratory setup logistics, planning of research aims
Name:	Karen Keenan
Project Role:	Co-Investigator
Nearest person month worked:	12
Contribution to Project:	Write/review IRB and resubmission, Developing new templates for database to store data variables collected, Data collection forms, Development of Operator Readiness Report
Name:	Mita Lovalekar
Project Role:	Co-Investigator
Nearest person month worked:	12
Contribution to Project:	Write and review IRB and IRB Submission, Weekly meetings to discuss protocol development, TCONs with PHC, All planning of research aims study design and statistics, Development of USASOC wide survey

Name:	Takashi Nagai
Project Role:	Co-Investigator
Nearest person month worked:	12
Contribution to Project:	Protocol development, Review IRB, Planning Research aims.
Name:	Nick Heebner
Project Role:	Co-Investigator
Nearest person month worked:	9
Contribution to Project:	IRB and resubmission review, Protocol development, Lab setup,
Name:	Scott Lephart
Project Role:	Co-Investigator
Nearest person month worked:	9
Contribution to Project:	Oversight on protocol development
Name:	Andrew Simonson
Project Role:	Co-Investigator
Nearest person month worked:	3
Contribution to Project:	Planning all research aims, Laboratory setup, and operation.
Name:	Meleesa Wohleber
Project Role:	Co-Investigator
Nearest person month worked:	3
Contribution to Project:	Planning all research aims, Laboratory setup, and operations.
Name:	Meaghan Beck
Project Role:	Research Coordinator
Nearest person month worked:	3
Contribution to Project:	Meaghan Beck resigned her position at UPitt Dec. Assisted PI with IRB and with budget and administrative reports.
Name:	Rob Koronosky
Project Role:	Research Coordinator
Nearest person month worked:	3
Contribution to Project:	Assisting the PI with budget and administrative reports.

Name:	Thida San-Adams
Project Role:	Database Analyst
Nearest person month worked:	5
Contribution to Project:	Formatted UPittMED database to collect research data.
Name:	Shawn Eagle
Project Role:	Graduate Student Researcher
Nearest person month worked:	12
Contribution to Project:	Write and review IRB and resubmission, Weekly meetings to discuss protocol modifications, remote laboratory move and equipment set up and calibration.
Name:	Erin Pletcher
Project Role:	Graduate Student Researcher
Nearest person month worked:	12
Contribution to Project:	Write and review IRB and resubmission, Weekly meetings to discuss protocol modifications, remote laboratory move and equipment set up and calibration.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

University of Kentucky informed Pitt that they would no longer be able to support their portion of the research work as per the original subcontract due to a change in the focus of their work. As such the University of Pittsburgh identified individuals at Pitt and requested approval to perform in-house the portion of work that would have been subcontracted to the UK from July 1, 2016 through September 30, 2017. This request was sent to Mr. Lance Nowell July 13, 2016. We are still waiting for a response/approval.

What other organizations were involved as partners?

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

US Army Public Health Center, Aberdeen Proving Ground, MD 21010 Collaboration with Tyson Grier, Dr. Bruce Jones and MAJ Tanja Roy on the research aim study designs and development of the <i>USASOC Wide Physical Training and Injury Survey</i> used in Phase 4 Aim 1.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

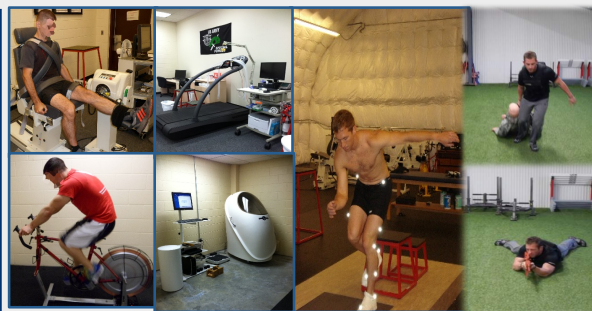


USASOC Injury Prevention and Human Performance Research

Background: Since April 2012, we have tested USASOC Operators at Fort Bragg with the purpose of identifying specific biomechanical, musculoskeletal, physiological, nutrition and performance characteristics that may be suboptimal and/or lead to a higher risk of injury and decreased physical performance

Key Findings to Date:

- Injury frequency- 18.9 injuries/100 subjects/year (76.9% preventable)
- Physical training was the most reported activity for preventable injuries.
- THOR3- 70.7% participation (3.3 ± 1.3 days for 12 months)
(Award # W81XWH-11-2-0020)



Study Aims

Phase 3 Aim 1: To evaluate the THOR3 HP training program to modify injury mitigating and performance characteristics previously identified in Phases 1-2 of research.

Phase 4 Aim 1: To evaluate the THOR3 HP training program to mitigate musculoskeletal injuries USASOC-wide.

Aim 2: To evaluate the THOR3 HP training program to improve injury mitigating musculoskeletal characteristics.

Aim 3: To test changes in biomechanical, musculoskeletal, physiological, tactical, nutritional, performance and injury characteristics across the deployment of a USASOC Operator.

Deliverables:

- Validation of the THOR3 HP training program to mitigate musculoskeletal injury characteristics and optimize Operator readiness
- Increase the physical readiness of the Soldier by reducing the risk of musculoskeletal injury, optimizing performance, and ensuring a physically viable force for deployment
- Develop and validate an injury prevention and performance optimization program that is culturally specific and dynamically responsive to the unique tactical demands of USASOC

Appendices None